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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,809	05/04/2001	Mark W. Perlin	PERLIN-10	8918

7590 06/14/2004

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/849,809

**Applicant(s)**

PERLIN, MARK W.

**Examiner**

Ardin Marschel

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 December 2003 and 26 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's election without traverse of Group I, specie of claim 8, (claims 1-4, 8, 9, 11, and 12) in the reply filed on 12/24/03 is acknowledged.

### **SEQUENCE RULE NON-COMPLIANCE**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). See, for example, the specification on pages 13, 22, and 23. However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statements under 37 CFR §§ 1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification. Applicant is also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action. It is noted that applicant previous submitted a document stating that no sequences were disclosed or claimed. It is acknowledged that the presently pending claims lack any sequence(s) therein, however, the specification at the above noted pages clearly disclose nucleic acid sequences which fall under these rules and result in a requirement for compliance with the sequence rules as summarized above.

### **PRIOR ART**

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 8, 9, and 11 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Ruano (P/N 5,427,911).

Ruano disclosed the combined or coupled methods of amplification and sequencing of DNA in both the title and abstract which is also the subject matter of the instant claims. The utilization of this methodology of the reference for criminal justice is described in column 3, lines 45-52, wherein law enforcement is cited which is deemed equivalent to the criminal justice usage as the instantly elected specie of invention. Identification for such law enforcement purposes inherently utilizes a database of genetic variations or polymorphic data as required also in instant claim 9. All of the summarized methods in column 1, line 59, through column 4, line 53, start with amplification which is also the first step in instant claim 1. These methods utilize primers as described specifically in the examples in columns 9-12, as well as chain terminating nucleotide analogs labeled to produce a collection of labeled nucleic acids products as also instantly claimed in claim 1, part (b). Size separation of the products is disclosed in the reference via electrophoretic methodology on sequencing gels as set

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forth, at various citations, for example, in column 10, lines 26-30. The detection of the total amount of label in said products occurs via autoradiography as shown in Figures 1A through 1D and Figure 3 as pictorial measurement as in instant claim 1, part (c). The darkness of each band in each lane of said Figures corresponds to the amount of terminating nucleotide which has been incorporated into labeled product as also required in instant claim 2. Each lane of said Figures also corresponds to a length of DNA sequence in sample DNA as may be read off for sequence determination as in standard sequencing procedures as also required in instant claim 3. The Figures depict a plurality of bases in the DNA sequence of the sample as also required in instant claim 4. Each lane in these Figures is a collection as instantly claimed and the sequence information is derived from combining four lanes, one for each nucleotide type, to determine DNA sequence information about the sample, thus anticipating step (d) of claim 1 also. These means are also those of instant claim 11. Thus, the instant claims are anticipated by the reference disclosure.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruano (P/N 5,427,911); taken in view of Lander et al. (P/N 6,692,909).

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Ruano has been summarized above as describing the basic instant invention.

Ruano, however, does not specifically disclose the thermocycler practice of embodiments of the instant claims or the combining means of instant claim 12.

The abstract of Lander et al. summarizes the invention therein disclosed as directed to the subject matter area of the instant invention as is Ruano as to applications of genetic sequence analysis. A major part of Lander et al. is directed to disease detection, however, the reference also includes the use of polymorphisms for crime scene investigation and for identification purposes as cited in column 10, line 29, through column 11, line 37, as is the elected specie of the instantly claimed invention. Lander et al. in column 17, line 38, through column 18, line 60, describe examples including the usage of thermocyclers as well as computer analysis to compare sequences which necessarily requires some type of memory of polymorphisms as required in instant claim 12. The automation of thermocyclers and computer analysis is motivated and suggested to improve the efficiency of analysis of large numbers of sequences in such genetic analyses.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the Ruano amplification and sequencing with the improvement of automation involving thermocyclers and computer analysis as in Lander et al. to improve such analysis efficiency to result in a reasonable expectation of success in practicing the instant invention.

No claim is allowed.

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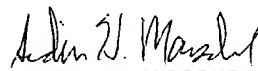
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

June 7, 2004

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER

6/7/04